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| RAMIREZ & SMITH PO BOX 341179 AUSTIN, TX 78734 | | | EXAMINER BOR, HELENE CATHERINE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto@isrlaw.com
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| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/792,029 | Applicant(s) DHAWALE ET AL. | |
| | Examiner HELENE BOR | Art Unit 3768 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 November 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>foreign patent, journal article and reference</u> . |

DETAILED ACTION***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claim 1-6, 8, 10-11, 15-23, 29-31, 41, 45, 46, 48, 50, 54, 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1) and further in view of Hamadeh'188 et al. (US Patent Application No. 2004/0088188 A1).

Claim 1, 10, 11, 16, 17, 22, 23, 40, 45, 50, 54 & 65: Reilly'463 teaches an apparatus comprising a dispensing station to receive a multidose vial of a radiotracer, and to dispense portions of the radiotracer, at least one positron emission tomography imaging system (Figure 1A, Element 40, Page 1, Para 004 & Page 6, Para 0061). Reilly'463 teaches an apparatus comprising a control system operably coupled to the local area network, to receive status information from, and send commands to, the at least one positron emission tomography imaging system and the dispensing station (Figure 1A, Element 38 & Page 6, Para 0061). Reilly'463 fails to teach the apparatus on a local area network and a plurality of positron emission tomography imaging systems. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to

Art Unit: 3768

maintain data integrity by having a network (Page 4, Para 0032). Reilly'463 teaches a medical radiopharmaceutical administration system comprising at least one positron emission tomography imaging system and operably coupled to a radioisotope producer (Page 1, Para 0010). Reilly'463 teaches a system comprising a chemical synthesizer operably coupled to the radioisotope producer, to receive the radioisotope, and to produce a radiotracer (Page 1, Para 0004). Reilly'463 teaches an apparatus, wherein the radiotracer further comprises fluorodeoxyglucose (Page 1, Para 0004). Reilly'463 teaches a medical radiopharmaceutical administration system, further comprising a quality control unit, to monitor the radionuclidic and chemical purity of the radiopharmaceutical that is dispensed by the dispensing station (Page 7, Para 0072).

Claim 2: Reilly'463 teaches an apparatus comprising a quality control unit, to monitor the radionuclidic and chemical purity of the radiotracer that is dispensed by the dispensing station, the quality control unit being operably coupled to the control system and operably coupled to the dispensing station (Page 5, Para 0054 & Page 7, Para 0072).

Claim 3: Reilly'463 teaches an apparatus, wherein the local area network is further operably coupled to a radioisotope producer and wherein the dispensing station receives the radioisotope from the radioisotope producer (Figure 1A, Element 40).

Claim 4 & 18: Reilly'463 teaches an apparatus, wherein the radioisotope producer further comprises a cyclotron (Page 1, Para 0004).

Art Unit: 3768

Claim 6 & 20: Reilly'463 teaches an apparatus, wherein the radioisotope producer further comprises a radioisotope generator (Page 1, Para 0004).

Claim 8 & 48: Reilly'463 teaches an apparatus, wherein a radioactivity shield surrounds portions of the apparatus that are radioactive (Page 1, Para 0010).

Claim 15: Reilly'463 teaches an apparatus, wherein the control system further comprises a computer system (Page 6, Para 0061).

Claim 24: Reilly'463 teaches an apparatus, wherein each positron emission tomography imaging system further comprises an injector system to extract at least one individual dose from the radiotracer and to inject the at least one individual dose into the living subject (Page 4, Para 0032).

Claim 41 & 46: Reilly'463 teaches a medical radiopharmaceutical administration system, wherein the local area network is further operably coupled to a cyclotron and wherein the dispensing station receives the liquid fluorodeoxyglucose (Figure 1A, Element 40, Page 1, Para 004 & Page 6, Para 0061).

2. Claim 5 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1) and in view of Hamadeh'188 et al. (US Patent Application No. 2004/0088188 A1) and further in view of Satyamurthy (Satyamurthy, N. et al. "Electric Generators for the Production of the Positron-Emitter Labeled Radiopharmaceuticals: Where Would PET Be Without Them?" *Clinical Positron Imaging*. Vol. 5, No. 5: 233-253, 1999.)

Claim 5 & 19: Reilly'463 fails to specifically teach an apparatus, wherein the radioisotope producer further comprises a linear accelerator. However,

Art Unit: 3768

Reilly'463 teaches an apparatus, wherein the radioisotope producer further comprises a cyclotron (Page 1, Para 004). However, Satyamurthy explains that linear accelerators are alternatives to cyclotrons. Since a cyclotron and linear accelerator perform similar functions with the same end results, it would be considered an equivalent expedient in the art. It would have been obvious to one of ordinary skill in the art to use either a cyclotron or a linear accelerator in integrated radiopharmaceutical production systems as equivalent expedients in the art.

3. Claim 7, 21, 26, 27-29, 31, 42, 47 & 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1) and in view of Hamadeh'188 et al. (US Patent Application No. 2004/0088188 A1) and further in view of Critchlow'930 et al. (US Patent No. 6,520,930 B2).

Claim 7, 21, 26, 42 & 47: Reilly'463 and Hamadeh'188 fail to teach the use of wheels. However, Critchlow'930 teaches the apparatus mounted on wheels (Figure 6D). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Critchlow'930 in order to increase the mobility of the apparatus (Col. 18, Line 40-47).

Claim 27: Reilly'463 teaches a system, wherein the portions of the system that are radioactive further comprise the dispensing station and the quality control unit (Page 6, Para 0061 & Page 7, Para 0072).

Claim 28: Reilly'463 teaches a system, wherein the dispensing station receives

Art Unit: 3768

the liquid radiopharmaceutical from the radioisotope producer (Figure 1A, Element 40 & 46).

Claim 29: Reilly'463 teaches a medical radiopharmaceutical administration system, wherein the radioisotope producer further comprises a cyclotron (Page 1, Para 0004).

Claim 31: Reilly'463 teaches a system, wherein the radioisotope producer further comprises a radioisotope generator (Page 1, Para 0004).

4. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1) and in view of Hamadeh'188 et al. (US Patent Application No. 2004/0088188 A1), in view of Critchlow'930 et al. (US Patent No. 6,520,930 B2) and further in view of Satyamurthy (Satyamurthy, N. et al. "Electric Generators for the Production of the Positron-Emitter Labeled Radiopharmaceuticals: Where Would PET Be Without Them?" *Clinical Positron Imaging*. Vol. 5, No. 5: 233-253, 1999.)

Claim 30: Reilly'463 fails to specifically teach an apparatus, wherein the radioisotope producer further comprises a linear accelerator. However, Reilly'463 teaches an apparatus, wherein the radioisotope producer further comprises a cyclotron (Page 1, Para 004). However, Satyamurthy explains that linear accelerators are alternatives to cyclotrons. Since a cyclotron and linear accelerator perform similar functions with the same end results, it would be considered an equivalent expedient in the art. It would have been obvious to one of ordinary skill in the art to use either a cyclotron or a linear accelerator in

Art Unit: 3768

integrated radiopharmaceutical production systems as equivalent expedients in the art.

5. Claim 9, 12-13, 35, 36, 38, 43, 49, 51, 54, 56, 58, 61-63, 65, 66-68, 70-77, 79 & 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1) and in view of Hamadeh'188 et al. (US Patent Application No. 2004/0088188 A1) and further in view of Tamaki'1989 (Tamaki et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989). Reilly'463 teaches the prior art method and a new method for calculating in the injection system. It would have been obvious to one of ordinary skill in the art to substitute the volume calculation for the prior art time calculation as taught in Reilly'463 because both methods are acceptable known methods of calculation.

Claim 9, 12, 35, 38, 43, 49, 51, 55, 56, 58, 61-63, 66, 67, 70, 72, 74, 75 & 79:

Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamaki'1989 and Hamadeh'188 in order to have higher quality images (Page 1308, Right Column). Reilly'463 teaches an apparatus, wherein each positron emission tomography imaging system further comprises an injector system to extract at least one individual dose from the radiotracer and to inject the at least one individual dose into the living subject

Art Unit: 3768

(Page 4, Para 0032). Reilly'463 also fails to teach the physiological monitoring system. Tamaki'1989 teach a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

Claim 13: Reilly'463 teaches an apparatus, wherein the amount of each individual dose is calculated based on the radioactive half-life of the radiotracer, the projected time of injection into a living subject and high level descriptors of the living subject (Page 6, Para 0064).

Claim 36: Reilly'463 teaches a system, wherein the radioisotope producer is selected from the group consisting of a cyclotron, and a linear accelerator, and wherein the dispensing station receives from the radioisotope producer (Page 1, Para 004).

Claim 68: Reilly'463 teaches an apparatus, wherein the amount of each individual dose is calculated based on the radioactive half-life of the radiotracer, the projected time of injection into a living subject and high level descriptors of the living subject (Page 6, Para 0064).

Claim 71: Reilly'463 teaches a system, wherein the injector is operable to inject individual doses of a radiopharmaceutical into a patient (Page 4, Page 0032).

Claim 73 & 80: Reilly'463 teaches a system, wherein the radiotracer further comprises fluorodeoxyglucose (Page 1, Para 0004).

Claim 76: Reilly'463 teaches a system, further comprising a computer system

Art Unit: 3768

operably coupled to the local area network, to control dispensing and injection of an individual dose of a radiopharmaceutical into a living subject and to control radiological scanning of the living subject (Page 6, Para 0061 & 0064).

Claim 77: Reilly'463 teaches a computer-accessible medium having executable instructions to manage radiotracer production (Page 6, Para 0061). Reilly'463 teaches executable instructions capable of directing a processor to perform receiving radiotracer material request information; determining amount of radioactivity needed from the request information; sending production instructions including the amount of radioactivity and the amount of radiotracer to a cyclotron and a synthesis unit; and sending instructions to the dispensing station (Page 6, Para 0065 & Page 7, Para 0072).

6. Claim 33, 32, 37 & 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1), in view of Hamadeh'188 et al. (US Patent Application No. 2004/0088188 A1), in view of Critchlow'930 et al. (US Patent No. 6,520,930 B2) and further in view of Tamaki'1989.

Claim 33: Tamaki'1989 teach a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

Claim 32: Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET

Art Unit: 3768

imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamki'1989 and Hamadeh'188 in order to have higher quality images (Page 1308, Right Column).

Claim 37 & 57: Reilly'463 and Hamadeh'188 fail to teach the use of wheels.

However, Critchlow'930 teaches the system mounted on wheels (Figure 6D). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Critchlow'930 in order to increase the mobility of the system (Col. 18, Line 40-47).

7. Claim 14, 25, 39, 44, 52, 53, 59, 60, 64, 69 & 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1), in view of Hamadeh'188 et al. (US Patent Application No. 2004/0088188 A1), in view of Tamaki'1989 (Tamaki et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989) and further in view of Kroll'869 et al. (US Patent Application No. 2005/0288869 A1).

Claim 14, 25, 39, 44, 52, 53, 59, 60, 64, 69 & 78: Reilly'463 fails to teach an apparatus that uses the patient's weight. However, Kroll'869 teaches wherein the high level descriptors of the living subject further comprise the weight, sex and physical dimensions of the living subject (Figure 2, Element 120). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006). Reilly'463 fails to

Art Unit: 3768

teach a system that uses the patient's weight. However, Kroll'869 teaches, wherein the high level descriptors of the living subject further comprise the weight, sex and physical dimensions of the living subject (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

8. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1), in view of Hamadeh'188 et al. (US Patent Application No. 2004/0088188 A1), in view of Tamaki'1989, in view of Critchlow'930 et al. (US Patent No. 6,520,930 B2) and further in view of Kroll'869 et al. (US Patent Application No. 2005/0288869 A1).

Claim 34: Reilly'463 fails to teach a system that uses the patient's weight. However, Kroll'869 teaches wherein the amount of each individual dose is calculated based on type of radiopharmaceutical, a predefined parametric equation, clinical protocol being followed and high level descriptors of the living subject, wherein the high level descriptors of the living subject further comprise the weight, sex and physical dimensions of the living subject (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

Art Unit: 3768

9. Claim 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1), and further in view of Haines et al. (US Patent No. 6,529,692).

Claim 81: Reilly'463 teaches a computer-accessible medium having executable instructions to manage radiotracer production (Page 5, Para 0051 & Page 6, Para 0061). Reilly'463 fails to teach how to specifically perform the dose activity calculations. However, Haines'869 teaches executable instructions capable of directing a processor to perform calculating a required radiotracer dose activity (Figure 5) and comparing a total activity available in the multidose portion of the radiotracer to the required radiotracer dose activity (Page 6, Para 0068). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006). Reilly'463 fails to teach notifying of a shortage. However, Haines'692 teaches using a notification system to notify the user when consumables are low or out (Col. 8, Line 15-34). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Haines'692 in order to assist the user in ordering consumables (Col. 1, Line 63-67).

Claim 82: Reilly'463 fails to teach notifying of a shortage. However, Haines'692 teaches using a notification system to notify the user when consumables are low or out (Col. 8, Line 15-34). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Haines'692 in order to assist the user in ordering consumables (Col. 1, Line 63-67).

Art Unit: 3768

Claim 83: Reilly'463 fails to teach notifying the outside supplier. However, Haines'692 teaches using a notification system to notify outside suppliers when consumables are low or out (Col. 8, Line 15-34). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Haines'692 in order to assist the user in ordering consumables (Col. 1, Line 63-67).

10. Claim 84 & 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1), in view of Hamadeh'188 et al. (US Patent Application No. 2004/0088188 A1), in view of Tamaki'1989 and further in view of Tuttle (EP 0542565 A1).

Claim 84: Reilly'463 teaches a computer-accessible medium having executable instructions to manage radiotracer injection, the executable instructions capable of directing a processor (Page 6, Para 0061). Reilly'463 teaches injecting the radiotracer into a patient (Page 4, Para 0032). Reilly'463 fails to teach scanning procedures. However, Tamaki'1989 teaches initiating scanning of the patient after a first predefined time (Page 1303, Left Column) and introducing a stress into the patient (Page 1303, Left Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column). Reilly and Tamaki'1989 fail to teach the stress is induce pharmaceutically but by exercise. However, Tuttle teaches pharmacological stress testing that offers advantages over the conventional exercise stress test (Abstract). It would have been obvious to one of ordinary skill in the art to substitute the exercise stress test as taught by

Art Unit: 3768

Tamaki'1989 with the pharmacological stress test as taught by Tuttle as an alternative in the art to exercise stress tests (Page 2, Line 12-13) and allow for testing of patients who can not perform the exercise (Page 2, Line 9-11).

Claim 85: Reilly'463 teaches a computer-accessible medium, wherein the computer-accessible medium further comprises instructions capable of directing a processor to perform injecting the radiotracer into patient (Page 4, Para 0032). Reilly'463 fails to teach scanning procedures. However, Tamaki'1989 teaches imaging the patient after a second predefined time (Page 1303, Left Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

Response to Arguments

11. Applicant's arguments, see Page 26-27, filed 11/27/2007, with respect to the drawings and the claims have been fully considered and are persuasive. The objections of drawings and claims have been withdrawn.

12. Applicant's arguments, see Page 47, filed 11/27/2007, with respect to the rejection(s) of claim(s) 1-85 under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as detailed above. The Applicant presented the argument that the local area network is not taught by Reilly'463. The Examiner agrees however notes that Hamadeh'188 et al. (US Patent Application No. 2004/0088188 A1) reference was used in a 103(a) to remedy that. The Applicant presents the argument that Reilly'463 does not teach

Art Unit: 3768

at least one positron emission tomography imaging system but only the imaging procedure of a positron emission tomography (PET). The Examiner contends that to perform the imaging procedure of a positron emission tomography, one must have a positron emission tomography system and that the existence of the system is inherent to carry out the disclosed PET imaging procedure. The Applicant presented the argument that since Reilly'463 did not disclose a problem with data integrity as disclose in Hamadeh'188 that there is no reasoning to combine the teachings. The Examiner respectfully disagrees as motivation to combine references can come from either reference and Reilly'463 does not have to disclose a problem in order for a proper 103(a) rejection to be applied. The Applicant argued hindsight reasoning in regards to the Examiner's search. The Applicant claimed "a local area network coupled to at least one positron emission tomography imaging system". The Examiner is required to conduct a search regarding the Applicant's claimed invention as required. Furthermore the Examiner contends that a search report does prove hindsight reasoning but rather the motivation applied in combining the references. The Applicant argues that the Office Action merely recites the benefits of "data integrity" with no reason as to why the recited benefits are particularly useful or beneficial to the invention. The Examiner contends that "maintaining data integrity" is beneficial to a healthcare facility who would not want such critical data integrity comprised as it would be detrimental to patient care. The Applicant argues that various elements such as "quality control" and "chemical purity" are not disclosed in Reilly. The Examiner disagrees even though Reilly does not use

Art Unit: 3768

the same terms as the Applicant claims, the elements are analogues. The Applicant argued that equipment is singular and does not cover the claim subject matter. The Examiner contends that Hamadeh'188 discloses any number of the imaging equipment and that according to *Cambridge Grammar of the English Language* on Page 326, "equipment has no plural counterpart"¹. Even though Hamadeh'188 did not use the term "equipments", does not mean that Hamadeh'188 did not intend the use of multiple imaging systems. The Applicant presented the argument that Reilly'463 states that "control 38" is adjusted by a computer but is not applicable to the claim language "control system further comprises a computer system." The Examiner disagrees. The claim language states that the system comprises a computer system, which is broad enough to be reasonably interpreted to be reading on the teachings of Reilly'463's control being adjusted by the computer. The Applicant argues that Reilly'463 does not teach the chemical synthesizer. The Examiner disagrees. On Page 1, Para 004 Reilly'463 teaches a "cyclotron equipped with a unit to synthesize the FDG molecule". The Applicant argues that Reilly'463 and Hamadeh'188 do not teach the physiologic monitoring system, which is why Tamaki'1989 was applied to address this deficiency. The Applicant argues that Reilly'463 teaches away from "the amount of each individual dose is calculated based on...the projected time of injection into a living being." The Examiner disagrees. On Page 6, Para 0064, Reilly'463 states, "Thus, it is no longer necessary to calculate and wait for the precise moment in time". Reilly'463 is saying it is "no longer necessary".

¹ See attachment. Rodney Huddleston et al. *Cambridge Grammar of the English Language*.

Art Unit: 3768

Reilly'463 does not say that the calculation is impossible or not useable just simply no longer necessary. Prior to that Reilly'463 goes into detail explaining the prior art method on Page 1, Para 0007. It would have been obvious to one of ordinary skill in the art to substitute the volume calculation for the prior art time calculation as taught in Reilly'463 because both methods are acceptable known methods of calculation. The Applicant argues that a skilled person would not look to a second patent to solve a problem already solved by a first patent. The Examiner disagrees that the combination of the references is doing such. In reviewing the examples provided, Reilly'463 is solving the problem of administering the radiopharmaceutical safely. While Kroll'869 addresses the proper dosing of the radiopharmaceutical. Reilly'463 measures the total radiation of the volume of radiopharmaceutical and further teaches controlling the flow rate (Page 6, Para 0064). Reilly'463 teaches the calculated volume but fails to teach how to specifically derive the volume. Kroll'869 provides the information necessary to solve the problem of the accurately dosing the patient based on the patient's sex, weight, etc. The Applicant stated, the Examiner failed to make the Haines'692 of record. The Examiner has corrected this error.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

Art Unit: 3768

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768